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Arlington Courthouse Plaza 1, Suite 1400
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Arlington, VA 22201

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,039,931

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,039,931, which claims a method of using the human drug product EOVIST® (gadoxetate disodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,698 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,698 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 8, 2009, (74 Fed. Reg. 38660). Under 35 U.S.C. § 156(c):

Period of Extension	=	RRP - PGRRP - DD - ½ (TP - PGTP)[1]
	=	3,818-791- 0 - ½ (3,450- 791)
	=	1,698 days (4.7 years)

Since the regulatory review period began January 21, 1998, before the patent issued (March 21, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 21, 1998, to and including March 21, 2000, is 791 days; this period is subtracted for the number of days occurring in the regulatory review period according to the FDA determination of the length of the regulatory review period which occurred on and before the patent grant date.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was

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[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP). See 37 C.F.R. § 1.775(d)(1)(iii).

made.
Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,039,931
Granted:	March 21, 2000
Original Expiration Date[2]:	March 21, 2017
Applicant:	Heribert Schmitt-Willich et al.
Owner of Record:	Bayer Schering Pharma Aktiengesellschaft
Title:	Derivitized DTPA Complexes, Pharmaceutica Agents Containing These Compounds, Their Use and Processfor for Their Preparation
Product Trade Name:	EOVIST® (gadoxetate disodium)
Term Extended:	1,698 days
Expiration Date of Extension:	November 13, 2021

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: EOVIST® (gadoxetate disodium)
Docket No.: FDA-2009-E-0020